

§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25, (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002.

(b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.

(c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a “failed to register” or “failed to list” status as applicable.

The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until the required information is submitted to and processed by FDA.

[77 FR 45943, Aug. 2, 2012]

§ 807.35 Notification of registrant.

(a) The Food and Drug Administration will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment

must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[69 FR 11312, Mar. 10, 2004, as amended at 77 FR 45943, Aug. 2, 2012]

§ 807.37 Public availability of establishment registration and device listing information.

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA Web site, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.

(b) The following listing information will not be available for public inspection or posted on the FDA Web site:

(1) For contract manufacturers, contract sterilizers, and private label manufacturers, the proprietary or brand name(s) under which a device is marketed and the FDA-assigned premarket submission number, if this information would reveal a confidential business relationship;

(2) FDA-assigned listing numbers.

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§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Procedures for Foreign Device Establishments

§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures in this section, § 807.41, and subpart B of this part. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of FDA for matters relating to the registration of device establishments and the listing of device products.

(b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its ini-

tial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.

(d) The device establishment registration and device listing information shall be in the English language.

[66 FR 59160, Nov. 27, 2001, as amended at 77 FR 45944, Aug. 2, 2012]

§ 807.41 Identification of importers and persons who import or offer for import.

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing